JUN - 2 2000

K001058

Premarket Notification [510(k)] Summary

SUBMITTED BY:
Kedly Incorporated
920 S. Highway Drive
St. Louis, MO 63026
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CONTACT PERSON:
Randall J. Krohn

DATE OF PREPARATION
March 31, 2000

TRADE NAME:
AUDIOscreener OAE+ABR

COMMON NAME:
Otoacoustic Emissions Test Instrument / Evoked Response Auditory Stimulator

CLASSIFICATION NAME:
Audiometer (per 21 CFR section 874.1050) Panel 77 Product Code EWO

Evoked Response Auditory Stimulator (per 21 CFR section 882.1900) Panel 84 Product Code GWJ

PREDICATE DEVICES:
Kedly Audioscreener OAE (K000184)
Natus Algo-2 (K936039)
Sonamed Clarity System II (K952080)

DEVICE DESCRIPTION:
The Audioscreener OAE+ABR is a Distortion Product Otoacoustic Emissions and Audiotory Brainstem Response testing device to be used in the evaluation of hearing function. This device is essentially the Audioscreener OAE unit with additional software and hardware included to perform the Auditory Brainstem Response test.

INTENDED USE:
The Audioscreener OAE+ABR is to be used to measure otoacoustic emissions from the human ear and audiometric brainstem response from the inner ear. This device is intended for use by trained health care professionals (for example, an Audiologist) to measure cochlear and auditory nerve function. The device may be used in a hospital, clinic, or physician or audiologist office setting. The device's test functions measure and record distortion product otoacoustic emissions (DPOAE), which are evoked by the

presentation of pure tones, and auditory brainstem response (ABR) signals, which are evoked by the presentation of clicks or tone pips.

TECHNOLOGICAL CHARACTERISTICS:
The Audioscreener OAE+ABR is similar in its intended use to predicate devices and existing methodologies. In addition, the device complies with the following safety and performance standards as applicable to its classification:

UL 2601-1 Medical Electrical Equipment Part 1: General Requirements for Safety 1st ed. 1997-10

CSA 22.2 No. 601.1 Medical Electrical Equipment Part 1: General Requirements for Safety-M90

IEC60601-1-2 Medical Electrical Equipment Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests 1st ed. 1993-04

ANSI S3.6 Specification for Audiometers (sections 4-10 as applicable) 1996

IEC 60601-2-40 Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment (1998-02)

FDA Electroencephalograph Devices Guidance for 510(k) Content Draft Document Version 1.0 November 3, 1997

IEC 645-3 Audiometers Part 3: Auditory Test Signals of Short Duration for Audiometric and Neuro-Otological Purposes (1994-10)

IEC 60601-2-26 Particular Requirements for the Safety of Electroencephalographs (1994-04)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2000

Mr. Randall J. Krohn
Kedly Incorporated
920 S. Highway Drive
St. Louis, MO 63026

Re: K001058
Trade Name: AUDIOscreener OAE + ABR
Regulatory Class: II
CFR: 874.1050
Product Code: 77 EWO, 84 GWJ
Dated: March 31, 2000
Received: April 10, 2000

Dear Mr. Krohn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K001058

Device Name: Audioscreener OAE+ABR

Indications for Use:

The Audioscreener OAE+ABR may be used for patients of all ages, from newborn infants through adults. The Distortion Product Otoacoustic Emissions and Auditory Brainstem Response tests are indicated for use in screening individuals for hearing loss for whom behavioral audiometric responses are deemed to be unreliable, such as in infants, young children, and uncooperative or cognitively impaired adults.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

Morris Waxler 6/2/2000

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001058

(Optional Format 3-10-98)